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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,488	11/20/2001	Yasuhiro Sando	15162/04050	8768

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SIDLEY AUSTIN LLP
717 NORTH HARWOOD
SUITE 3400
DALLAS, TX 75201

EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/988,488

Applicant(s)

SANDO ET AL.

Examiner

Natalia Levkovich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-18,20-27,50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-18,20-27,50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks dated 06/12/2006 have been acknowledged by the Examiner and entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-18, 20-27 and 50-51 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4, as amended, recites '...a confluence area in which the specimen and the reagent flowing from the first and the second flow passes join ...', the confluence area 'being located downstream from the first and the second flow passes; a third flow pass in which the liquid mixture flows and light from a reaction of the liquid mixture is generated, the third flow pass being connected to the confluence area and being located downstream from the confluence area and on a different level from the first and the second flow passes...'. The claim does not clearly set forth structural cooperation between the 'confluence area' and the third flow pass. First, it is unclear

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how one should construe what 'a different level' is, since the orientation in space of the apparatus, in general, and of its elements, in particular, is not identified in the claims.

Second, it is not clear whether the 'confluence area' is located on the same 'level' with the third pass, or with the first and second ones, since the claim recites the third pass being connected to the 'confluence area' (rather than through, or via the 'confluence area').

Claims 4, 6 and 17 recite: '...wherein the light generated in the third flow pass goes through the third flow pass in an extension direction of the third flow pass and exits to a light detection area'. The aforementioned claims do not set forth the structure which would provide for the recited functionality.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in the 03/07/2006 Office Action.

5. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Liu ('807) or Liu ('207) in view of Knapp et al ('471), and further in view of Chow (US 6167910).

As was previously discussed in the 03/07/2006 Office Action, both Liu ('807) and Liu ('207) disclose 'flow passes' with inlet and outlet ports (see, for example, Figures 1-3 of Liu '807, or Figure 3 of Liu '207). The devices of Liu comprise only a single flow pass, rather than a branched ones (such as, for example, two flow lines joined to form a third

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line). However, such branched flow lines are well known in the art. Knapp et al. disclose a flow-through optical analysis device in which various fluids are conducted to the sensing area via branched flow paths, valves and micro-pumps. Figure 4A shows, for example, inlets 406, 408 in communication with channels 414, 416 ['first and second flow passes' – Ex.] forming a join / ['confluence area', not indexed – Ex.] with the main channel 404 ['third flow pass' – Ex]. It would have been obvious to one of ordinary skill in the art to modify the sensors of Liu to further include multiple branched flow channels with corresponding inlets and flow controls (such as valves and micro-pumps), in order to enable introduction of multiple samples /reagents.

Although Liu ('807) or Liu ('207) modified by Knapp do not teach sample or reagent channels to be in different parallel planes with the main / 'mixture' channel, such layouts are commonly used in the art (see, for example, Figures 1A and 3A of Chow. It would have been clearly within the skill of the art at the time the invention was made to have arranged the sample / reagent supply channels in a different parallel plane(relative to the plane where the main / mixture / detection channel is located), in the modified apparatuses of Liu, in order to achieve a more compact layout for the device and in order to provide more convenient access to the main channel needed for optical connections.

6. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu ('807) in view of Knapp et al ('471).

See the appropriate paragraphs of the 03/07/2006 Office Action.

7. Claims 6-18, 20 and 22- 27 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Liu ('207) in view of Knapp et al ('471).

See the appropriate paragraphs of the 03/07/2006 Office Action.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liu ('207) in view of Knapp et al., and further in view of Chen ('453).

See the appropriate paragraphs of the 03/07/2006 Office Action.

9. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu ('207) in view of Knapp et al ('471), and further in view of either one of Neuschafer et al and Burgess, Jr. et al.

See the appropriate paragraphs of the 03/07/2006 Office Action.

Response to Arguments

10. Applicant's arguments filed on 06/12/2006 have been fully considered but they are not persuasive and moot in view of new grounds of rejection.

Applicant argues that the 'flow pass of Liu '807 has areas where the light is not detected or the excitation light is not applied'. Examiner notes such a limitation is not recited in the instant claims.

Applicant also argues that Liu '807 'does not disclose first and second flow passes in which a specimen and a reagent ...flow, nor does Liu '807 disclose a confluence area in which the specimen and reagent join...' Examiner agrees. Liu does not teach branched supply lines converging into the detection channel. Such structures are disclosed by Knapp (see the discussion above).

Applicant argues (in reference to claims 6 and 17) that 'Knapp does not teach that the distance between the confluence area and the detection area needs to be small. Examiner notes that such limitation is not recited in these claims.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

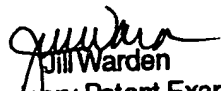
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
Supervisory Patent Examiner
Technology Center 1700